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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,453	10/07/2003	Randal A. Stevens	34597.1	4505

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EXAMINER

PADGETT, MARIANNE L

ART UNIT	PAPER NUMBER
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1762

DATE MAILED: 12/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/680,453

Applicant(s)

STEVENS ET AL.

Examiner

Marianne L. Padgett

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/7/2003 & 2/5/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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1. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The use of relative terms that lack clear beats and downs in the claim itself, or in a clear definition in the description or in a cited piece of relevant prior art, is vague and indefinite in all the independent claims see "high" in "high gloss exterior finish" and "thin" in "thin uncured layer". It is noted that page 1, lines 3-7 and the top page 4, give some examples of layer thicknesses, however they are not provided as a definition for "thin" layer, nor is it clear whether they are referring to cured or uncured layers' thickness, but the former seems the more likely context. Also, the use of "stereolithographically" to describe "resin" may also be considered relative, because there is no specific definition describing what resins a stereolithographic resin may be, as it is relative to the intended end use and other factors what resins may be employed therefore.

In claim three is unclear, as it refers to a step (f), which does not exist. Similarly, claims 6 & 10, steps (a) refer to nonexistent steps (g).

In the independent claims, the steps referring to "removing any excess..." can be considered confusing or ambiguous as written, because they could be referring to the same action that refers to draining resin, since it is clearly removing excess and there is no necessity in the claims of when the draining or removing steps are performed, as there are no temporal or antecedent limitations that require any particular order. Note as the claims do not specify for what purpose the substance is excess, the step could even refer to cutting off or trimming resin in various places to further shape the product, which might be considered reasonable for a product that was not produced stereolithographically, which is not required in any way in any of the claims.

2. The disclosure is objected to because of the following informalities: on page 4, lines 21-23 of the description there appear to be a mixture of manufacturers and trade names of resins, where it is

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uncertain how many of the listed names are of resins and it is unknown what compositions these trade names may encompass. It is improper to have insufficiently defined trade names in a description.

Also further proofreading is recommended, for example on page 2, line 7, are the slashes intended to mean or are they be more commonly used division symbol. On line 9, see "Further more", which is usually one word. Appropriate correction is required.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanna in view of Farnworth et al.

Hanna teaches making hearing aid shells via stereolithographic techniques, where in order to produce biocompatible products, it is necessary to detoxify by extracting cytotoxins remaining from the stereolithographic polymerization procedures, which may involve UV curing. Several different means of doing so are taught, which are inclusive of extracting with alcohols, such as isopropyl alcohol alone, or with use of such alcohols in ultrasonic bath, with teachings on sufficient times for these procedures to extract unpolymerized residues from the stereolithographically constructed hearing aid shells, which

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affects required detoxification. Thereafter, post UV curing finishes the cure of the produced shell, and it is further taught that it is common practice to further coat hearing aid shells, such as with UV curable lacquer. In Hanna, see the abstract; figures 2-3 & seven; [0001]; [0005]; [0009-10]; [0012]; [0014-15]; [0022-23]; [0030-33]; especially [0039]; and [0042-49].

While Hanna uses an analogous series of steps to applicants' procedure of UV polymerization and extraction/removing for constructing the hearing aid shell, they differ by not giving any similar details for their generically disclosed UV curable coating of that shell. However, Farnworth et al. teach a procedure for coating stereolithographic structures, where they teach their process is applicable to any structure made by stereolithography, which is advantageous for smoothing the surface to get rid of crevices at the layer interfaces on the surface, which are undesirable as they may be unsightly and they may collect dust, dirt and moisture. When Farnworth et al. lift the structure in its final form from the stereolithographic polymer bath, instead of washing any unpolymerized resin from the crevices, they merely drain the excess polymer from the structure so as to leave a coating that fills the crevices, reading on applicants' "thin uncured layer", then they cure by either UV laser or broad beam or flood type UV radiation, after which typical final curing procedures, including washing with alcohol and UV post curing may be performed. In Farnworth et al., see the abstract; figures 1 & 6-10; col. 1, line 7-18; col. 2, lines 13-25 & 61-67; col. 3, line 41-col. 4, line 23; col. 5, line 52-col. 6, line 17; col. 8, line 49-col. 9, line 5+; col. 11, line 35-col. 14, line 68, especially col. 12, lines 1-40 & 58-67, col. 13, lines 5-35 & 48-col. 14, lines 13 & 39-57.

It would have been obvious to one of ordinary skill in the art to use the surface smoothing coating procedure of Farnworth et al. to produce the stereolithographic hearing aid shells of Hanna, in order to achieve the advantageously smooth surface as taught in Farnworth et al., as it provides a specific procedure for creating the suggested UV cured coating, and further provides the advantageous elimination of crevices that can collect dirt, as well as being economical in its use of photo polymeric resin, which is not wasted by washing away, and its consideration of how this coating procedure enhances wall

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uniformity, affecting the size of final object. It would have been further clear to one of ordinary skill in the art, that one would use the detoxification procedures (i.e. use of alcohol in ultrasonic bath or to chemically extract undesirable unpolymerized residues after the initial UV cure) of Hanna on the so produced coating of the stereolithographically produced hearing aid shell, in order to have a biocompatible product after final cure.

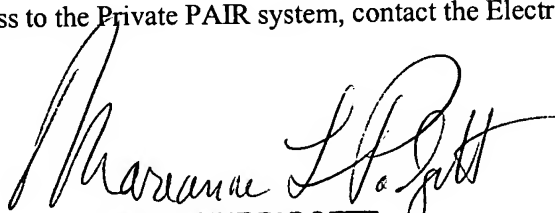
5. Other art of interest includes Sauerhoefer (5482659) who teaches a stereolithographic process including post-processing steps of submerging in alcohol with ultrasonic agitation, drying & UV post-treatment curing. Also Hanna (US 666-0208 B2) is equivalent to the EPA reference to the same inventor discussed above. Johnson et al. (2005/0175925 A1) teach a specific composition and structure of photocurable material for making three the objects with generally smooth surfaces when cured, which may be used for making housings for hearing aids (abstract & [0011], etc.).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne L. Padgett whose telephone number is (571) 272-1425. The examiner can normally be reached on M-F from about 8:30 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks, can be reached at (571) 272-1423. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MLP 12/4/2005


MARIANNE PADGETT
PRIMARY EXAMINER